IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Inventor ..... Shaw, David Peter
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Examiner ..... Ann M. Schillinger
Attorney's Docket No. PL10-002
Title: ..... Prosthetic Valves for Medical Application

DECLARATION OF DAVID PETER SHAW UNDER 37 CFR 1.132

I, David Peter Shaw, citizen of New Zealand, hereby declare:

1. I reside at 183 Cossars Road, Tai Tapu, R.D. 2, Christchurch, New Zealand and am a Surgeon currently in practice in Christchurch, New Zealand as a consultant cardiothoracic surgeon. I hold the degrees of Bachelor of Medicine, Bachelor of Surgery and Bachelor of Medical Science and I am a fellow of the Royal Australasian College of Surgeons. My surgical training was undertaken in New Zealand with a final year as a clinical fellow at the Brigham and Womens Hospital, Boston, USA (part of the Harvard Medical School group). I have been in practice in New Zealand and Australia for the last 15 years as a consultant cardiothoracic surgeon. I have also acted/currently act as an expert consultant for Emphasys Medical Inc and Genesee Biomedical. I am the inventor and holder of several medical device patents for devices for clinical use.

2. I am the sole inventor of the subject matter claimed in the present US Patent Application No. 10/563,387. The valve the subject of the present application is not yet in clinical use, so I cannot supply

clinical data. However, since the device is to be used in my own specialist field, I am familiar with the range of ways in which it can be used.

3. The primary function of a heart valve is to check backflow; obviously a valve structure with multiple perforations would not function as designed without these perforations being sealed or too small to allow significant blood flow. This situation is analogous to that of early vascular grafts, the primary function of which is to contain blood and thus multiple perforations would not meet this function, not to mention obvious technical difficulties that would be encountered.

4. Historically, the first attempts at knitted/woven synthetic grafts utilised women's nylon stockings. The obvious problem of immediate leakage was solved by "pre-clotting" the graft. There were two ways of performing this, the first was to take a blood sample from the patient prior to any anticoagulation (usually Heparin) being given. This blood was placed in a dish along with the vascular graft and the scrub nurse "kneaded" the blood through the graft. Within a few minutes the blood would clot within the interstices of the graft. This led to a sealed tube. In time the body's endothelium and fibrous tissue replaced this "clot". Should the patient have already received a large dose of anticoagulation during the procedure, another method was frequently employed. Blood was drawn from the patient, this was placed in a bowl and the

nurse "kneaded" the blood through the graft as before. The difference here was that the heparinised blood soaked graft was then placed in a "flash autoclave," the high temperature causing the proteins to coagulate and thus sealing the graft interstices. Similarly in time these interstices would be replaced by the patients' own endothelialised tissues.

5. The evolution of commercial knitted/woven grafts consigned homemade grafts from women's nylon stockings to a footnote in history. The early commercial grafts were a similarly porous structure and the same processes were employed. The next step in evolution was for these grafts to be packaged in a sterile manner with a coating that would undergo dissolution in the body to be replaced with the patients' own tissues. This step obviated the need to pre-clot the graft and thus saved operative time. Materials for this coating included gelatine and collagen.

6. The development of knitted/chain-mail valve leaflets present the same range of options as the knitted/woven grafts discussed above: at the option of the surgeon using the valve, the grafts could be pre-clotted, i.e., provided to the surgeon without a coating and pre-clotted using the patient's blood as discussed in paragraph 4 above. Another possibility is that the valves could be supplied pre-packaged with an existing coating in the manner discussed in paragraph 5 above. A third possibility, which does not exist for the knitted/woven synthetic grafts, is that if a valve in accordance with

the present invention is provided using a very fine mesh size, I consider that a biodegradable coating may not be necessary at all.

7. It will be a matter of choice by the surgeon selecting and using the valve, whether an uncoated valve, or a very fine mesh valve, or a pre-coated valve, is used.

8. I emphasise that pre-coating the valves with an absorbable sealant of the type described in paragraph 5 above is not an essential part of my invention, but is simply one of a range of choices available to a surgeon.

9. I have been warned and am aware that willful false statements and the like herein are punishable by fine or imprisonment, or both (18 USC § 1001) and may jeopardize the validity of the present application or any patent issuing thereon. All statements made herein which are of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated: 3/9/2010 By: _____
David Peter Shaw